

REMARKS

This paper is a response to the outstanding office action of February 1, 2010. After amendment, claims 1-3, 6-7 and 89-104 are pending in the present application. Claims 94-102 were previously added as new claims to provide further dependent claims reflective of the restricted invention and new claims 103 and 104 provide further limitations to the hydrophilic crosslinking agent of claim 1. In claim 1, Applicants previously amended the term *comprising* which is an open term to the term *consisting essentially of*, a term which is more limited in scope. Notwithstanding the Examiner's comments regarding same, the term *consisting essentially of* is used and is meant to describe biodegradable or bioerodible crosslinked diblock polymers according to the present invention which contain diblock (AB) polymers which are hydrophilically crosslinked and are biodegradable/bioerodible. The compositions as claimed are consistent with their use in biological systems and in certain preferred aspects are useful in inhibiting the formation or reducing the likelihood of adhesions at risk to be formed in patients subsequent to medical procedures, especially surgical procedures. Support for the presentation of amended claim 1 and new claims 103 and 104 can be found throughout the originally filed application and claims and in particular, in the specification, *inter alia*, at page 29, middle of the page, page 37 bottom, page 38 top, page 43, bottom, page 46, bottom, page 49, bottom, page 55, top. No new matter has been added by way of the present amendment.

Claims 4-5 and 8-88 were previously canceled without prejudice as was all previously canceled subject matter. It is respectfully submitted that the amended claims as presented herein meet the requirements of 35 U.S.C. and are clearly patentable over the art of record.

A review of the present claims in comparison to the disclosure of Nair, U.S. patent no. 5,429,826 ("Nair") cited against the present invention shows that the present invention is clearly novel and non-obvious over the cited art of Nair. In particular, the present invention, as claimed, relates to the inclusion of hydrophilic crosslinking agents in polymeric compositions according to

M19-106.rceamendment non-final 6-10 -6-

the present invention in order to make the resulting gels and viscous solutions more compatible with an aqueous solution while still exhibiting structural integrity, such that the resulting polymeric materials are particularly useful to inhibit or reduce the likelihood of adhesion formation in a patient, for example, subsequent to a medical procedure, especially including a surgical procedure. In contrast to the present invention, the polymers of Nair are crosslinked with hydrophobic or oleophilic crosslinking agents in aqueous solution, in order to form micelles and "lock" the polymers into micellar form using the hydrophobic crosslinking agents which are disclosed therein. The invention of the present application as currently claimed is clearly patentably distinguishable over the teachings of Nair.

The Examiner has rejected the present invention under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103 as being obvious over the teachings of Nair for the reasons set forth in the February 2010 office action on pages 3-5. It is respectfully submitted that the presently pending claims are patentable over the disclosure of Nair. Applicants shall address each of the Examiner's rejections in the sections which follow.

The Rejection of Previously Pending Claims 1-3, 6-7 and 89-102 as being anticipated by Nair

The Examiner has rejected previously pending claims 1-3, 6-7 and 89-102 under 35 U.S.C. §102(b) as being anticipated by Nair for the reasons which are presented in the office action on pages 3-4. Applicants have amended previously pending claim 1 and accordingly, submit that the presently claimed invention is patenably distinguishable over Nair.

In particular, the present invention as claimed is directed to novel biodegradable and/or biocrodible hydrophilically crosslinked diblock polymers *consisting essentially of* AB diblocks which are crosslinked with hydrophilic crosslinkers, where A is a polyester block and B is a polyether (poly)oxyalkylene block which is end-capped with a non-reactive group. In the present invention in amended claim 1, the term *consisting essentially of* is given its ordinary meaning,

M19-106.rceamendment non-final 6-10 -7-

and compositions according to the present invention provide AB diblock polymeric compositions which are crosslinked with hydrophilic crosslinkers. These polymeric diblock compositions are useful primarily in medical applications as they take advantage of a biodegradable polyester block to which is bonded a polyoxyalkylene block, such materials being particularly useful in applications which inhibit or reduce the likelihood of the formation of adhesions as otherwise disclosed. The compositions, because of their limited molecular weight and viscosity (compared with chain-extended polymers which are often used in films) may be formulated as viscous polymers and/or gels and injected into a site within a patient with limited invasiveness (such as using laparoscopic techniques) in order to inhibit and/or reduce the likelihood of adhesion formation subsequent to a medical procedure in the patient, especially after a surgical procedure.

Nair does not anticipate the present invention. In particular, Nair teaches the use of diblock polymers which comprise at least one hydrophilic block and at least one hydrophobic block, the polymeric compositions being crosslinked *in aqueous solution* to produce a stable, crosslinked micellar structure. In Nair, the polymeric materials prior to crosslinking are placed in aqueous solution along with hydrophobic (oleophilic) crosslinking agents and are crosslinked in aqueous solution to form micelles of "locked in" physicochemical structure. That Nair requires hydrophobic crosslinkers is evidenced by the fact that the motivation to provide structured micelles *requires* that the crosslinking agents selectively dissolve into the hydrophobic portion of the diblock which, in aqueous solution, is in the form of a micelle (hydrophilic blocks in association with the aqueous solution and hydrophobic crosslinking agents in association with the hydrophobic block within the interstices of the micelles formed in aqueous solution away from association with the hydrophilic blocks and the aqueous solution. Nair clearly does not disclose the use of a hydrophilic crosslinking agent because to do that would disrupt the critical structural features of the micellar formation of Nair.

As Nair states in the abstract of the invention:

There is provided copolymer particles wherein the particles are derived from chemically fixed micelles that comprise a copolymer. The copolymer is an

amphiphilic block or graft comprising a water soluble component and an oleophilic component that can be crosslinked in an aqueous environment; *and the oleophilic component is crosslinked*. The particles can be dispersed in an aqueous continuous phase. The particles can contain other materials associated with the oleophilic component such as biochemical agents or other materials such as photographic materials such couplers and dyes.

It is quite clear that Nair was providing materials which were in crosslinked micellar form, and in order to provide that micellar form in aqueous solution, the crosslinking agents are required to be hydrophobic or oleophilic, so that these agents could selectively associate with the hydrophobic (oleophilic) portion of the micelle and react with that the hydrophobic portion of the molecule in micellar form. Otherwise, if hydrophobic crosslinking agents were not used, the micelle would not form properly and the resultant material would have a compromised micellar structure, a teaching which Nair avoids.

In contrast to the teachings of Nair, the present invention relies on crosslinking reactions using hydrophilic crosslinking agents, rather than hydrophobic crosslinking agents. By using hydrophilic crosslinking agents, the polymeric materials which are produced exhibit structural integrity consistent with the formation of viscous solutions and/or gels, resulting in favorable chemical characteristics for the delivery of the materials to a surgical site within a patient and the inhibition or reduction in adhesion formation, the motivation for producing compositions according to the present invention. Given the fact that the present invention is directed to chemical compositions that are clearly distinguishable from the compositions of Nair, no anticipation is made out. Applicants respectfully request that the Examiner should withdraw her rejection that the presently claimed invention is anticipated by Nair.

The Rejection of Previously Pending Claims 6 and 92-102 as being Obvious Over Nair

The Examiner has rejected the previously pending claims 6 and 92-102 as being obvious over Nair for the reasons which are presented in the office action on pages 5-6. Applicants

respectfully traverse the Examiner's rejection. The teachings of Nair which are presented hereinabove are referenced here. Essentially, Nair discloses diblock polymers comprising a hydrophobic (oleophilic) portion and a hydrophilic portion which form micelles in aqueous solution wherein the micellar structure is established and "locked in" by crosslinking the hydrophobic portion of the molecule using a hydrophobic crosslinking agent. In contrast, as discussed above, the presently claimed compositions rely on the use of hydrophilic crosslinking agents to provide a structural integrity of the final polymeric compositions which is consistent with the formation of viscous solutions and/or gels which are compatible and useful for delivery to a patient with minimum invasiveness so as to inhibit and/or reduce the likelihood of adhesion formation subsequent to a medical procedure, especially including a surgical procedure.

Nair does not render the present invention obvious. As discussed hereinabove, Nair is directed to a chemistry which provides micellar structures, the result of a diblock polymer as disclosed being polymerized using a hydrophobic crosslinking agent, not a *hydrophilic* crosslinking agent as is presently claimed. The result is a micellar composition of a chemical structure significantly distinguishable from the present invention. In essence, Nair *teaches away* from the present invention, because the use of a hydrophilic crosslinking agent as used in the present invention is actually *inconsistent* with the function of the Nair chemical compositions which is to provide micellar structures which may be used to deliver biochemical agents or alternatively, to be used to deliver photographic materials such as couplers and dyes. These chemical components are hydrophobic and can be readily incorporated into the hydrophobic pocket of the micellar chemical structures of Nair.

That there is no motivation in Nair to provide the present compositions resides, at least in part, in the fact that Nair did not mention or even contemplate the uses of the presently chemistry- i.e. for inhibiting adhesion formation for which the presently claimed compositions are particularly well suited. The fact is that there is no teaching of hydrophilic crosslinking agents in Nair. In addition, Nair clearly teaches away from the use of hydrophilic crosslinking

agents by virtue of the polymeric chemistry taught and the uses for that polymer chemistry. Given those facts and the absence of motivation to provide the chemistry of the present invention because of a complete absence of teaching, recognition or understanding of the basic problem (e.g., post-surgical adhesion formation) for which the present compositions are formulated, Applicants respectfully submit that the presently claimed invention is clearly non-obvious over the teachings of Nair. Applicants respectfully submit that the teachings of Nair do not make out a credible rejection that the presently claimed invention is obvious and unpatentable over those teachings.

It is respectfully submitted that the present invention is clearly non-obvious over the teachings of the art, where, as here, the prior art cited against the invention (Nair) teaches that the presently claimed compositions should not be made because the use of the chemistry of the present invention *contravenes* the rationale and motivation for the teachings presented in the cited prior art. The presently claimed compositions stand in complete contravention to the teachings of Nair given that the use of a presently claimed hydrophilic crosslinking agent, used in an aqueous solution as taught by Nair, would destroy the structural integrity of the polymeric composition which Nair teaches. If anything, the teachings of the prior art fully support the patentability of the present invention.

Consequently, for the reasons which are presented hereinabove, it is respectfully submitted that the claimed invention is in compliance with the requirements of 35 U.S.C. Applicants respectfully assert that the claims set forth in the amendment to the application of the present invention are now in condition for allowance and such action is earnestly solicited.

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Applicants have added two dependent claims (previously paid for) in this amendment. No fee is due for the presentation of this amendment. Small entity status pertains to this application. A petition for an extension of time is enclosed as is authorization to charge the petition fee to Deposit Account 04-0838. The Commissioner is authorized to charge any deficiency in fee or to credit any overpayment to deposit account 04-0838.

Respectfully submitted,

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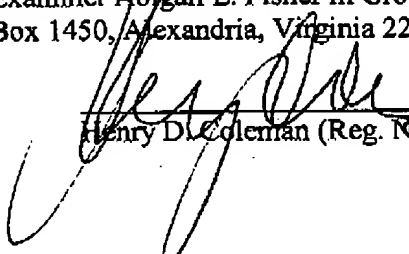
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Dated: June 30, 2010

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I hereby certify that this correspondence is being sent by facsimile transmission to Examiner Abigail L. Fisher in Group Art Unit 1616, United States Patent Office, P.O. Box 1450, Alexandria, Virginia 22313-1450, on July 1, 2010.


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M19-106.rceamendment non-final 6-10 -12-